



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

12/22/91
724

PURGED *EX*

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

cc: HF1-35/FOI Staff
DWA

November 21, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 10

Al J. Kaiser
President
Kaiser Farms, Inc.
585 Seagull
Mosinee, Wisconsin 54455

Dear Mr. Kaiser:

This letter is in reference to your firm's product, "Wisconsin Ginseng," which is being marketed and distributed under claims that it can prevent or treat numerous disease conditions.

The promotional material for this product, entitled "Consumer's Guide to Ginseng Products," includes references to heart disease and cancer, implying a positive connection. The brochure claims that your product has "been proven to have the following effects: cholesterol inhibitor, strong detoxin--protects against the harmful effects of alcohol and other toxins." The next paragraph states:

Many of the active ingredients and compounds found in ginseng have anti-cancer activity. These clinical trials also showed that ginseng has a protective effect against cancer.

Furthermore, the section "Which ginseng is best for me" discusses stress (under "Wisconsin Ginseng") including references to

Page Two

Al J. Kaiser

November 21, 1997

Too much stress contributes to high blood pressure and cardiovascular problems, has been implicated in cancer, and is a direct cause of...gastric ulcers...insomnia, migraines, along with other diseases.

Your promotional literature, "Ginseng, The King of Herbs," contains numerous drug claims. Reference is made specifically to pages 2 ("Adaptogen Effect"), 3 ("Effects of Ginseng on Stress and Fatigue"), 6 ("Effects of Ginseng on Aging"), 7 ("Effects of Ginseng on Diabetes Mellitus"), 8 ("Effects of Ginseng on Alcohol Detoxification"), 9 ("Effects of Ginseng on the Liver"), 10 ("Effects of Ginseng on Sexual Function and Menopausal Symptoms"), 11 ["Effects of Ginseng on Hypertension (Arteriosclerosis)"], 12 ("Effects of Ginseng on Anemia and Radioprotection"), and 13 ("Effects of Ginseng on Cancer"). Claims, such as the following include:

- * "Most extensively studied have been the beneficial effects of ginseng on stress, alcohol detoxification...radiation exposure, and such various disorders as diabetes mellitus, cancer, arteriosclerosis, hypertension, hepatic disorders and anemia."
- * Ginseng "sets up a universal defense system capable of increasing the body's resistance to physical factors such as...radiation, to chemical factors such as poisons and cancer-inducing substances and to biological factors such as bacteria and viruses."
- * "Antioxidant effects also seem to account for other beneficial effects of ginseng reported such as...the protective effects on irradiation."
- * Ginseng can treat diabetes.
- * Ginseng reduces alcohol intoxication, lowers blood alcohol levels, and enhances the elimination of alcohol from the blood.

These claims are subject to the July 19, 1983, Final Rule: "Orally Administered Drug Products for the Relief of Symptoms Associated with Overindulgence in Alcohol and Food for Over-the-Counter (OTC) Human Use; Decision on Ingredients Intended to Minimize or Prevent Inebriation"

Page Three

Al J. Kaiser

November 21, 1997

(copy enclosed). In that rule, the Agency determined that no ingredient is regarded as safe and effective for use in an OTC drug either as a sobriety aid or to minimize or prevent inebriation. The Agency also expressed concern in the rule that such products may present a potential health hazard particularly when motorists rely on unsubstantiated claims that the products will prevent or minimize an inebriated state.

- * "...[G]inseng treatment increased the excretion of lead and mercury, thus reducing the accumulation of the metals in the system. Ginseng also normalized an impaired immune system...as a result of heavy metal poisoning. ...[G]inseng exhibited beneficial effects on the detoxification of a carcinogenic compound, benzopyrene."
- * "...[U]se ginseng as part of emergency treatment to restore blood pressure...and heart attacks...ginseng improved overall condition of patients suffering from arteriosclerosis significantly. In the case of patients having hyperlipidemic conditions...ginseng lowered the total blood cholesterol.... The beneficial effects of ginseng on lipid metabolism can help control hypertension."
- * "[G]inseng is also claimed to have anti-cancer properties."

Your promotional literature includes such terms as "adaptogen" or "fibromyalgia" which imply disease conditions that are treated by your product. However, neither of these terms are found in the current medical dictionaries.

The web site contains the above claims as well as more extensive testimonials implying use of your product in the treatment of such diseases as diabetes, lichen planus, and arthritis.

"Wisconsin Ginseng" is a drug [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. This product is also a "new drug" [Section 201(p) of the Act] and, therefore, may not be marketed in the United States without an approved new drug application (Section 505 of the Act).

Page Four

Al J. Kaiser

November 21, 1997

This drug is also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the product has been manufactured using "Quality controlled FDA approved manufacturing" and that the product is safe and effective for its intended uses when, in fact, this has not been established [Section 502(a) of the Act].

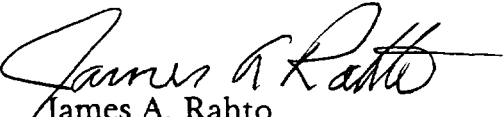
This letter is not intended to be an inclusive review of all of the claims made in your labeling and promotional literature for your product. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

CAH/ccl

Enclosure: Final Rule, 7/19/83